K032815-S1

FEB 12 2004

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Attachment VIII 510(k) Summary

Sponsor:	Precision Surgery Limited 318 Pheasant Court Fond du Lac, WI 54935 Phone: 920.223.0547, Fax: 920.223.0551
Contact Person:	Kamaljit S. Paul, MD
Proprietary Trade Name:	Precision Surgery Limited Variable and Fixed Cervical Plate System
Device Description:	The Precision Surgery Limited Variable and Fixed Cervical Plate System includes plates and screw components. There are three types of plates available, two variable and one fixed. Primary and rescue screws are available.
Intended Use:	The Precision Surgery Limited Variable and Fixed Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. WARNING: The Precision Surgery Limited Variable and Fixed Cervical Plate System is <u>not</u> intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Materials:	The Precision Surgery Limited Variable and Fixed Cervical Plate components are manufactured from titanium alloy (ASTM F136).
Substantial Equivalence:	Documentation was provided which demonstrated the Variable and Fixed Cervical Plate System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, anatomic sites, performance and material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2004

Precision Surgery Limited
C/o Ms. Karen E. Warden, MEBE
8202 Sherman Road
Chesterland, Ohio 44026

Re: K032815
Trade/Device Name: Variable and Fixed Cervical Plates
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 29, 3003
Received: January 6, 2004

Dear Ms. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment III Indications for Use

510(k) Number:_____

Device Name: **Variable and Fixed Cervical Plates**

Indications for Use:

The Precision Surgery Limited Variable and Fixed Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The Precision Surgery Limited Variable and Fixed Cervical Plate System is <u>not</u> intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032815

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)